UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,049	11/28/2001	Jennifer L. Policky	PI-0072 USN	9619

22428 7590 09/17/2004

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,049	POLICKY ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1 to 56 are pending in the instant application.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1 to 7, 9, 11 to 19, 22, 25 to 28, 45 and 51, drawn to a polynucleotide, a polypeptide, and methods of use, only in so far as they relate to SEQ ID NO:1.

Group II, claims 1 to 7, 9, 11 to 19, 22, 25 to 28, 46 and 52, drawn to a polynucleotide, a polypeptide, and methods of use, only in so far as they relate to SEQ ID NO:2.

Group III, claims 1 to 7, 9, 11 to 19, 22, 25 to 28, 47 and 53, drawn to a polynucleotide, a polypeptide, and methods of use, only in so far as they relate to SEQ ID NO:3.

Group IV, claims 1 to 7, 9, 11 to 19, 22, 25 to 28, 48 and 54, drawn to a polynucleotide, a polypeptide, and methods of use, only in so far as they relate to SEQ ID NO:4.

Group V, claims 1 to 7, 9, 11 to 19, 22, 25 to 28, 49 and 55, drawn to a polynucleotide, a polypeptide, and methods of use, only in so far as they relate to SEQ ID NO:5.

Group VI, claims 1 to 7, 9, 11 to 19, 22, 25 to 28, 50 and 56, drawn to a polynucleotide, a polypeptide, and methods of use, only in so far as they relate to SEQ ID NO:6.

Group VII, claim 8, drawn to a transgenic organism, only in so far as it relates to SEQ ID NO:1.

Group VIII, claim 8, drawn to a transgenic organism, only in so far as it relates to SEQ ID NO:2.

Group IX, claim 8, drawn to a transgenic organism, only in so far as it relates to SEQ ID NO:3.

Group X, claim 8, drawn to a transgenic organism, only in so far as it relates to SEQ ID NO:4.

Group XI, claim 8, drawn to a transgenic organism, only in so far as it relates to SEQ ID NO:5.

Group XII, claim 8, drawn to a transgenic organism, only in so far as it relates to SEQ ID NO:6.

Group XIII, claims 10 and 29 to 44, drawn to an antibody and methods of use, only in so far as they relate to SEQ ID NO:1.

Group XIV, claim 10 and 29 to 44, drawn to an antibody and methods of use, only in so far as they relate to SEQ ID NO:2.

Group XV, claim 10 and 29 to 44, drawn to an antibody and methods of use, only in so far as they relate to SEQ ID NO:3.

Group XVI, claim 10 and 29 to 44, drawn to an antibody and methods of use, only in so far as they relate to SEQ ID NO:4.

Group XVII, claim 10 and 29 to 44, drawn to an antibody and methods of use, only in so far as they relate to SEQ ID NO:5.

Group XVIII, claim 10 and 29 to 44, drawn to an antibody and methods of use, only in so far as they relate to SEQ ID NO:6.

Group XIX, claims 20 and 21, drawn to an agonist and method of use, only in so far as they relate to SEQ ID NO:1.

Group XX, claims 20 and 21, drawn to an agonist and method of use, only in so far as they relate to SEQ ID NO:2.

Group XXI, claims 20 and 21, drawn to an agonist and method of use, only in so far as they relate to SEQ ID NO:3.

Group XXII, claims 20 and 21, drawn to an agonist and method of use, only in so far as they relate to SEQ ID NO:4.

Group XXIII, claims 20 and 21, drawn to an agonist and method of use, only in so far as they relate to SEQ ID NO:5.

Group XXIV, claims 23 and 24, drawn to an antagonist and method of use, only in so far as they relate to SEQ ID NO:6.

Group XXV, claims 23 and 24, drawn to an antagonist and method of use, only in so far as they relate to SEQ ID NO:1.

Group XXVI, claims 23 and 24, drawn to an antagonist and method of use, only in so far as they relate to SEQ ID NO:2.

Group XXVII, claims 23 and 24, drawn to an antagonist and method of use, only in so far as they relate to SEQ ID NO:3.

Group XXVIII, claims 23 and 24, drawn to an antagonist and method of use, only in so far as they relate to SEQ ID NO:4.

Group XXIX, claims 23 and 24, drawn to an antagonist and method of use, only in so far as they relate to SEQ ID NO:5.

Group XXX, claims 23 and 24, drawn to an antagonist and method of use, only in so far as they relate to SEQ ID NO:6.

The inventions listed as Groups I to XXX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The six amino acid sequences presented in SEQ ID Nos:1 to 6 of the instant application do not reflect a single inventive concept. The instant specification indicates that these six sequences correspond to the amino acid sequences of six different, naturally-occurring human G protein-coupled receptors. The "BACK GROUND OF THE INVENTION" section of the instant specification concedes that isolated nucleic acids encoding human G protein-coupled receptors, and the receptors encoded thereby, were well known in the art before the time that the instant invention was made. The six different amino acid sequences recited in the claims lack unity of invention because the instant specification does not identify a special technical feature

that is shared by these six sequences and which distinguishes them as a group from those human G protein-coupled receptors known in the prior art.

The isolated polypeptide of each of inventions I to VI and the transgenic organism of each of inventions VII to XII do not reflect a single inventive concept because the defining polypeptide in each of these inventions occurs in nature. A naturally occurring polypeptide can not serve to link a composition comprising that polypeptide in an "isolated" state with a transgenic organism expressing that polypeptide since it is the state of purity that distinguishes the polypeptide of each of inventions I to VIII from the prior art and this special technical feature is not present in a transgenic organism of each of inventions VII to XII.

The isolated polypeptide of each of inventions I to VI, the antibodies of each of inventions XIII to XVIII, the agonists of inventions XIX to XIV and the antagonists of inventions XXV to XXX do not reflect a single inventive concept because the amino acid sequence that structurally defines a polypeptide of each of inventions I to VI is not present in, or reflected by the structure of an antibody, an agonist or an antagonist that binds thereto. It is well known in the art that the portion of a protein that is recognized by an antibody that binds thereto is usually no more than five or six amino acids in length, and there is no suggestion in the specification that the "isolated" G protein-coupled receptors described therein are distinguished from the prior art by every combination of six or more contiguous amino acid residues presented in SEQ ID Nos:1-8. It is also well known that G protein-coupled receptors and their native ligands tend to be chemically unrelated. Further, as indicated above, it is the state of purity that

distinguishes the polypeptide of each of inventions I to VIII from the prior art and this special technical feature is not reflected in the antibodies of inventions XVII to XXIV, the agonists of inventions XIX to XIV and the antagonists of inventions XXV to XXX which would readily bind to each of those polypeptides in their native environment.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kunz Gary can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1646